REMARKS / ARGUMENTS

Applicant asserts that the present final rejection is premature, and, therefore, requests withdrawal of the finality of the rejection.

Claim 4 was present in the application at the time that the prior rejection was made, and there was no indication that Applicant intended to abandon its subject matter. The Examiner has indicated that claim 4 was not included in the prior rejection and that the previous amendment necessitated the new grounds of rejection because "there was no subject matter in claim 4 that even identified administration of imatinib." However, every claim from which claim 4 could have properly depended, related to and required the administration of imatinib to a patient for the treatment of pulmonary hypertension. Since claim 4 was clearly intended to further limit one of the pending claims, each of which required the administration of imatinib to a patient for the treatment of pulmonary hypertension, Applicant reasonably understood not including claim 4 in the art rejection to mean that claim 4 was patentable over the cited art and that the art rejection could be overcome by limiting the main claim to the scope set forth in claim 4.

If Applicant had corrected the dependency of claim 4 and argued against the rejection of claim 10 in response to the Office action of April 1, 2008, the inclusion of previously pending claim 4 in the present rejection would clearly be a new rejection that should have not have been a final rejection. The result should not be different because Applicant included the limits of claim 4 in the base claim to overcome the rejection. Therefore, Applicant asserts that the present rejection under 35 USC 103(a) is a new rejection that was not necessitated by the previous amendment, and that the finality of the rejection is premature.

The present claim amendments bring the claims back to the original scope prior to Applicant's misunderstanding of the rejection. Applicants believe that entry of this amendment and withdrawal of the finality of the rejection would serve the purposes set forth in MPEP 706.07. Accordingly, Applicant requests withdrawal of the finality of the art rejection.

Claims 10, 2, 5 and 7 were rejected as failing to meet the enablement requirement of 35 USC 112, first paragraph. Applicant requests reconsideration and withdrawal of this rejection for the reasons that follow.

As noted by the Examiner the term "treatment" is defined in the specification as covering both "curative" treatment and "prophylactic" treatment as each of those terms are defined in the specification. At page 12 of the specification, prophylactic treatment is defined as preventing the onset or recurrence of pulmonary hypertension.

The Examiner agrees that the present specification is enabling for curative treatment, but contends that the disclosure does not enable prophylactic treatment. However, the Examiner provides no scientific rational to explain of why a compound which has efficacy for treating ongoing episodes of the condition would not also prevent the onset or recurrence of the condition.

It is the Examiner's burden to explain why they doubt the truth or accuracy of statements in the disclosure and to back up assertions with acceptable evidence or reasoning. See, In re Marzocci, 169 USPQ 367, 369-370 (CCPA 1971). In this instance, the Examiner merely states that prevention is a more rigorous term that implies that neither a new onset or any recurrence of any episode will occur. However, Applicant asserts that the prophylactic treatment as defined in the present specification only requires that some new onsets or recurrences be prevented. Indeed, since the curative treatment is enabled, there is no reason to doubt that administration of imatinib would not also prevent some new onsets or recurrences. Therefore, the rejection under the enablement requirement of 35 USC 112, first paragraph, is improper. Accordingly, Applicant requests withdrawal of this rejection.

Claims 10, 2, 5 and 7 were rejected under 35 USC 103(a) over Goncharova et al, Tanabe et al, Zimmermann et al and Dingli et al. Applicant requests reconsideration and withdrawal of this rejection for the reasons that follow.

In response to the reasons that the Examiner asserts that the references provide a reasonable expectation that imatinib would be useful for treating PH found on page 10 of the Office action, Applicant makes the following comments:

1) The references do not implicate PDGFR in pulmonary hypertension. They merely report experiments that suggest that pathways involving PDGFR activity may be related to pulmonary hypertension or that PDGFR is overexpressed in PH. Neither suggests that PDGFR inhibition as a therapy to control PH.

2) Goncharova et al does not teach that imatinib inhibits cell proliferation and motility. As discussed below, it teaches that cell proliferation and motility are inhibited by rapamycin, which is not disclosed to target PDGFR.

3) Tanabe et al describes experiments which suggest that PDGFR may play a role in vasculature hypertensive diseases, but it does not reach the conclusion that inhibiting PDGFR may provide a therapeutic benefit for such diseases.

The assumption that pulmonary hypertension could be treated by controlling PSVM cell mitogenesis and that PVSM cell proliferation is central to the present rejection. However,

Goncharova et al clearly teaches that S6K1 plays a potentially important role in PSVM cell mitogenesis and that PVSM cell proliferation demonstrates high sensitivity to rapamycin, the specific inhibitor of S6K1. See, page L362, second full paragraph. In view of such disclosure, the reference would lead one of skill in the art to try to control pulmonary hypertension with S6K1 inhibitors like rapamycin, not with PDGFR inhibitors. Thus, Goncharova et al does not suggest to treat pulmonary hypertension by the present invention, but clearly leads the skilled artisan to take a different approach.

Tanabe et al discloses experiments which lead the authors to the conclusion: "These results suggest that stretch triggers the overexpression of PDGF-Rβ in vasculature hypertensive diseases. Thus, PDGF ligand receptor system may play a significant role in the development of several hypertensive diseases." However, such a disclosure is merely reporting experiments that suggest a correlation between PDGF-Rβ and vasculature hypertensive diseases, such as pulmonary hypertension. It does not suggest that the inhibition of PDGFR as an appropriate treatment for the condition. At best, it would be understood by the skilled artisan as suggesting that the connection between hypertensive diseases and PDGFR should be further investigated. However, such a disclosure does not provide the skilled artisan with a reasonable expectation that pulmonary hypertension could be treated by inhibiting PDGFR.

The cited references do no more than suggest a connection between PDGFR and pulmonary hypertension. This is merely an invitation to experiment which provides no basis to have a reasonable expectation that PDGFR inhibition would be useful for the treatment of pulmonary hypertension. Moreover, the combined disclosure of these references would not lead to the present invention, but instead would lead the skilled artisan to experiment with S6K1 inhibitors like rapamycin, not PDGFR inhibitors.

Zimmermann et al and Dingli et al are not alleged to overcome these shortcomings of the primary references. Therefore, Applicant asserts that the present invention is patentable over the combined disclosure of the references and requests withdrawal of the rejection under 35 USC 103(a).

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,

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